K040767

JUN - 7 2004

510(k) Summary
SYNCHRON® Systems HDL Cholesterol Reagent

1.0 **Submitted By:**

Annette Hellie
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Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
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2.0 **Date Submitted:**

March 24, 2004

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems HDL Cholesterol (HDLD) Reagent

3.2 **Classification Name**

Lipoprotein test system (21 CFR § 862.1475)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems HDLD Reagent	SYNCHRON Systems HDLC Reagent	Beckman Coulter, Inc.	K934045

5.0 **Description:**

SYNCHRON® Systems HDL Cholesterol (HDLD) Reagent, when used in conjunction with SYNCHRON® Systems Lipid Calibrator, is intended for the quantitative determination of HDL cholesterol in the high-density lipoprotein (HDL) fraction of serum or plasma on SYNCHRON Systems.

6.0 Intended Use:

SYNCHRON® Systems HDL Cholesterol (HDLD) Reagent, when used in conjunction with SYNCHRON® Systems Lipid Calibrator, is intended for the quantitative determination of HDL cholesterol in the high-density lipoprotein (HDL) fraction of serum or plasma on SYNCHRON Systems.

Clinical Significance:

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

	Similarities	
HDLD Reagent	Intended Use	Same as HDLC
	Liquid stable reagent	
	Differences	
HDLD Reagent	Methodology	HDLC is an indirect method, HDLD is a direct method
	Analytic Range	HDLC = 5 to 90 mg/dL HDLD = 5 to 135 mg/dL

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

Method Comparison Study Results

Instrument	Slope	Intercept	r	n	Comparison Method
SYNCHRON CX	0.991	2.2	0.956	63	SYNCHRON HDLC
SYNCHRON LX	0.973	0.5	0.972	66	SYNCHRON HDLC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 7 2004

Ms. Annette Hellie
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 South Kraemer Blvd.
PO Box 8000
Brea, CA 92821

Re: k040767
Trade/Device Name: SYNCHRON® Systems HDL Cholesterol (HDLD) Reagent
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: LBS
Dated: March 24, 2004
Received: March 25, 2004

Dear Ms. Hellie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040767

Device Name: **SYNCHRON® Systems HDL Cholesterol (HDLD) Reagent**

Indications for Use:

SYNCHRON® Systems HDL Cholesterol (HDLD) Reagent, when used in conjunction with SYNCHRON® Systems Lipid Calibrator, is intended for the quantitative determination of HDL cholesterol in the high-density lipoprotein (HDL) fraction of serum or plasma on SYNCHRON Systems.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Albert Sun

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040767